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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,363	05/25/2000	Barbara P. Wallner	I0248/7012 (ERG/MAT)	6092

7590

01/03/2003

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 01/03/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,363

Applicant(s)

WALLNER ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-19, 31 and 36-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 11-19, 31, 36, 37 and 40-51 is/are rejected.
- 7) ☒ Claim(s) 3-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. Claims 1, 19, 36, and 37 recite a new formula that was not explicitly recited in the specification as originally filed and embraces numerous compounds not embraced by the original claims. For example, as currently claimed, peptides comprising as many as 22 amino acid residues are embraced, whereas Formula II as recited in the original disclosure embraces only as many as twelve amino acid residues. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.
2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Compounds of Formula II as recited in instant claims 1, 19, 36, and 37 are not recited in the instant specification.
3. Claims 1-8, 11-19, 31, 36, 37, and 40-51 are objected to because of the following informalities: Claims 1, 19, 36, and 37 recite a structural formula referred to as "Formula II" which conflicts with the structural formula designated "Formula II" in the specification and in claims 38 and 39. Claims 1, 19, 36, and 37 should be amended so that different structural formulas are given different labels. Appropriate correction is required.
4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 11-19, 31, 36, 37, and 40-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 09/744,658 in view of O'Reilly et al or Brooks et al. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '658 application claims treating medical conditions including angiogenesis, neoplasm, tumors, and cancer by administering a DPP-IV inhibitor, preferably Val-boroPro. See claims 10, 13, and 20. The '658 application does not claim combining its DPP-IV inhibitors with antiangiogenic or anti-cancer compounds, does not claim combining its DPP-IV inhibitor administration with surgical treatment, and does not claim the subjects being treated for angiogenesis, neoplasm, tumors, or cancer as being otherwise free of symptoms calling for hemopoietic stimulation, as having normal hemopoietic activity, or as being HIV negative. O'Reilly et al (see, e.g., column 14, lines 20-27) and Brooks et al (see, e.g., column 8, lines 13-25) disclose that it is known to combine surgical, chemotherapeutical, and anti-angiogenic treatments in treating tumors. It would have been obvious to one of ordinary skill to combine the angiogenesis, neoplasm, tumor and cancer treatment claimed in the '658 application with other known methods of treating angiogenesis, neoplasm, tumors, and cancer, including surgery or treatment with other anti-tumor compounds including angiogenesis inhibitors, because O'Reilly et al and Brooks et al show that it is routine in the cancer therapy arts to combine treatments in order to optimize

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treatment of the cancer. It would have been obvious to one of ordinary skill in the art to treat angiogenesis, neoplasm, tumors, and cancer according to the claimed method of the '658 application in any subject, including those patients recited in instant claims 11, 16, and 17, because it is desirable to treat angiogenesis, neoplasm, tumors, and cancer in any patient in which the conditions are found, and because the hemopoietic activity or HIV status of such a patient would not have been expected adversely to affect the patient's ability to be treated in the claimed method of the '658 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1, 2, 11-19, 31, 36, 37, and 40-51 are directed to an invention not patentably distinct from claims 1-21 of commonly assigned 09/744,658. See the above provisional obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned 09/744,658, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

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A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

6. Instant claims 1-8, 11-19, 31, 36, 37, and 40-51 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/135,861 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, is deemed to disclose the claimed invention.

Instant claims 38 and 39 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/135,861 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose the compounds of Formula II in which A and A₁ can be any L- or D-amino acid. Note that the provisional application at page 2 and page 11 requires the amino acid attached to the N-terminus of A₁ to be a proline residue, which is not required by Formula II as recited in the instant claims. Note also that page 2, line 24, and page 11, line 22, of the provisional application explicitly require the amino acids present in the compounds of Formula II to be L-amino acids.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was

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published under Article 21(2) of such treaty in the English language.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 2, 11-19, 31, 36, 37, and 40-51 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/744,658 which has a common inventor with the instant application in view of O'Reilly et al or Brooks et al. See the above provisional obviousness-type double patenting rejection. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

9. Applicant's arguments filed November 14, 2002 have been fully considered but they are not persuasive.

The provisional obviousness-type double patenting rejection over copending application 09/744,658 is maintained. MPEP 822.01 does not authorize withdrawal of a provisional obviousness-type double patenting rejection unless it is the only remaining issue in the application, at which point the provisional rejection can be withdrawn and the application can be allowed. It should also be emphasized that in the interview on May 2, 2002, the examiner's position was that the claims of the '658 application would have to be amended so that the instant claims were no longer obvious over the claims of the '658 application. It is not relevant to the current provisional obviousness-type double patenting rejection that the claims of the '658 application may be amended to be obvious over the instant claims, because only one-way obviousness is required to support an obviousness-type double patenting rejection.

The requirement to show common ownership is maintained because Applicants' statement had not been received by the time it became necessary to prepare this Office action.

Because of the changes made to 35 U.S.C. 102(e) by the Intellectual Property and High Technology Technical Amendments Act of 2002 (H.R. 2215), copending application 09/744,658 is now provisionally available as prior art against the instant claims under 35 U.S.C. 102(e). The '658 application's disclosure of treating medical conditions including angiogenesis and tumors by administering a DPP-IV inhibitor, preferably Val-boroPro, is entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/097,376 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses this subject matter. See, e.g., page 5, lines 8-12, and claims 1, 10, and 13 of provisional application 60/097,376. The provisional obviousness rejection based upon copending application serial number 09/744,658 (see paragraph 8 above) could also be overcome by a showing of common ownership consistent

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with 35 U.S.C. 103(c). [Provisional application 60/097,376 does not disclose treating neoplasms or cancer, and accordingly for claims in the instant application limited to treatment of these medical conditions and otherwise entitled to the benefit of the filing date of provisional application 60/135,861, copending application 09/744,658 would not be provisionally available as prior art under 35 U.S.C. 102(e).]

In view of the new effective filing date analysis under 35 U.S.C. 119(e) set forth above, the WO Patent Application 00/10549 is not available as prior art under 35 U.S.C. 102(a) against instant claims 1-8, 11-19, 31, 36, 36, and 40-51. Accordingly, the rejections set forth in paragraphs 4 and 6 of the previous Office action and which relied upon this reference are withdrawn.

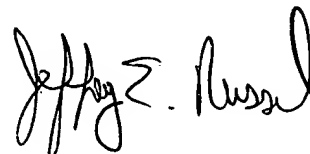
The obviousness rejection based upon the WO Patent Application 95/15309 in view of O'Reilly et al or Brooks et al and set forth in paragraph 5 of the previous Office action is withdrawn for the reasons given by Applicants at page 10, second and third paragraphs, of the response.

10. Claims 38 and 39 are allowed. Claims 3 and 8 would be allowable if rewritten to overcome the claim objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

December 31, 2002